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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,719	03/09/2001	Lewis T. Williams	2300-1624	9010

7590 07/16/2003

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	20

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,719	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-15* is/are pending in the application.

4a) Of the above claim(s) *9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-4 and 6-15 are pending in this application. Claims 9-15 stand withdrawn from consideration, and must be canceled in response to this final rejection. Claim 5 has been canceled.

Applicant's arguments filed 5/2/03 have been fully considered but they are not completely persuasive. Any rejection not repeated below has been withdrawn or overcome.

The request for a corrected filing receipt filed 5/02/03 appears to have been entered, and the information has been corrected in the PALM system.

The IDS filed 5/2/03 has been entered and considered. An initialed copy of the form PTO-1449 is included with this action.

The Statement of Deposit, and declaration of E. Scott has been entered and considered, and is sufficient to overcome the rejection based upon the deposit issue.

Rejections Maintained

Claims 1-4 and 6-8 remain rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or a well established utility for the reasons set forth in the previous office action.

Applicant argues that the two entries in Table 5, regarding the expression of SEQ ID NO: 222 in certain types of colon cells, are sufficient to provide utility for the polynucleotides being claimed. It is noted by the examiner, that the claims recite a large genus of polynucleotides who only need to have 50 nucleotides of SEQ ID NO: 222, which is very different than a single polynucleotide consisting of SEQ ID NO: 222. It is entirely unknown whether a representative number of the species that fall within the claim actually have the same expression pattern even in these three types of colon cells. These arguments are not commensurate in scope with the pending claims.

Even if the claims were to be limited to the polynucleotide described and tested, these arguments are not completely persuasive.

The specification, at page 25, sets forth that tissue typing for the identification of the developmental organ or tissue source of a metastatic lesion can be accomplished by identifying the level of expression of a polynucleotide in various tissue types, and that if the sequence is only

expressed in a single tissue type, it can be used in such assays. SEQ ID NO: 222 was not tested in a variety of tissue types: only colon cells, colon tumor, and colon metastasis. No other tissues, normal or otherwise, were tested for SEQ ID NO:222 expression levels.

The specification at page 28 sets forth criterion for differential expression diagnostics. It notes that for these types of diagnoses, the expression level of the polynucleotide should be compared between the suspected disease sample, a normal sample of the same tissue **and/or** other control cells. No other control cells were tested for SEQ ID NO: 222 expression levels.

The specification at page 36 discusses the diagnosis, prognosis and management of cancer, and notes that a polynucleotide of the invention identified as important for one type of cancer can have implications for development or risk of development of other cancers. SEQ ID NO: 222 was not tested for any relevance in other cancer types.

In Table 5, which Applicant relies upon in the arguments, the significance of these numbers is unclear. It would seem like SEQ ID NO: 222 is actually not discriminatory between normal colon tissue and colon tumor tissue- unless the sample is metastatic. The exact samples, conditions, and conclusions to be drawn from the information in Table 5 are not clear enough to derive a specific, substantial and credible utility for a polynucleotide consisting of SEQ ID NO:222, much less for the genus of undefined polynucleotides being claimed.

As set forth previously, The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The claims are drawn to isolated polynucleotides having part or all of a sequence selected from the group consisting of SEQ ID NO: 222. At page 5 of Table 1, the following information is set forth about SEQ ID NO: 222: it belongs in cluster 555911; It has a sequence name of RTA22200023F.f.21.P.SEQ; it is in the forward orientation; it has a clone ID of: M00055050:74; and can be found in library CH17COHLV. In Table 2 of the disclosure, SEQ ID NO: 222 is asserted to have some unspecified "significant homology" with two known sequences: AC007047, a hypothetical protein from Arabidopsis having no known or disclosed function, and

M24566, a tRNA-Glu-GAA gene from slime mold. In table 5 of the specification, SEQ ID NO: 222 is asserted to be present more often in colon metastasis cells than in normal colon cells or colon tumor cells. SEQ ID NO: 222 is not assessed or listed in any of tables 8-14, which purport to link sequences to disease states in actual patients.

All of the above information regarding the potential identity of any sequence encoded by SEQ ID NO: 222 was done by computer analysis, which was not born out by searches done by the examiner. None of the assertedly homologous proteins were found to be relevant hits when SEQ ID NO: 222 was searched using a Smith-Waterman Algorithm, or a BLAST-type algorithm. The elected polynucleotide was not tested for any particular activity in the specification. The only tissue specificity tests appear to have been done in three types of tissues, with no analysis of the presence or absence of SEQ ID NO: 222 in any other tissues. Therefore, it is difficult to interpret these result as being significant.

General uses of polynucleotides set forth in the specification, as filed, include chromosome mapping, to fish out full gene sequences, RFLP analysis, DNA fingerprinting, the expression of any encoded polypeptides, and identification of diseases linked to a sequence (pages 24-43). These general uses are not specific and substantial, as they do not require any one particular sequence. Further, they provide no specific information about any one sequence. For example, for the asserted utility of chromosomal mapping no particular chromosome, and chromosomal location has been assigned to any particular nucleotide sequence. Therefore one of ordinary skill in the art would have to perform additional tests to determine which specific chromosomal location is identified by each polynucleotide sequence disclosed, and further determine whether the particular sequence would be practical to use in chromosomal mapping studies..

The need for such further research and experimentation clearly indicates that the asserted utilities for the polynucleotides are not disclosed and therefore are not specific, substantial and credible utilities Further no well established utility is supported for any one polynucleotide. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world"

context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well-established for the compounds.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claim(s) 1-4 and 6-8 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1-4 and 6-8 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous office action.

Applicant presents a multiplicity of arguments regarding the court decisions cited by the Examiner in the previous action, without relating those arguments specifically to the fact pattern present in the instant application. As such, these arguments are not persuasive. Further, Applicants arguments are not commensurate in scope with the pending claims. If claims were to be presented that are limited to the sequence of SEQ ID NO:222, these arguments might be persuasive. However, none of the claims have such a scope, and for the reasons set forth previously, these claims lack written description in the specification as originally filed.

The claims are drawn to a genus of polynucleotides which comprise at least 50 nucleotides of SEQ ID NO:222, but have various other limitations regarding hybridization or identity to SEQ ID NO: 222. These claims read upon intact genomic material, or chromosomal material, having introns, promoters, enhancers, terminators etc which are not described in the

specification at all. These claims read upon any number of variations, fusions, deletions, insertions, etc of SEQ ID NO: 222 which are not specifically described. These claims read on related sequences from other species which are not described in the specification. Applicant has not addressed this issue.

No function for SEQ ID NO: 222 is identified in the specification, therefore Applicant cannot provide a partial structure in combination with functional language to claim a related genus of polynucleotides having a similar function. Applicant has not addressed this issue.

SEQ ID NO: 222 is a chemical structure, and Applicant has not set forth or described the various differing structures for the genus of polynucleotides falling within the scope of the claims. Therefore, the claims lack written description in the application as filed.

New Grounds of Rejection

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. *This is a new grounds of rejection based upon Applicant's amendments.*

Claims 1, 2 and 4 have been amended to recite that the polynucleotide comprises at least 50 contiguous nucleotides of SEQ ID NO: 222. This limitation of at least 50 is new, and appears to be new matter. The page and line pointed to by Applicant in support of this amendment (p30 line 4) has nothing to do with the length of polynucleotides. Applicant points out no other specific places in the specification for specific support of this amendment, an none is apparent to the examiner. Therefore this limitation is new matter.

Conclusion

The rejections based upon prior art are overcome in view of the amendment reciting a minimal length. However, this limitation is new matter. Therefore, if this limitation is removed, the art may be reapplied.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz

7/9/03

MARY K. ZEMAN
PRIMARY EXAMINER
1631